

#5

Substitute for form 1449A/PTO

**INFORMATION  
DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

SEP 1 0 2001

Complete if Known

Application Number	09/855,342
Filing Date	May 14, 2001
First Named Inventor	Caligiuri
Group Art Unit	812 1646 1642
Examiner Name	Not yet assigned
Attorney Docket Number	35784/209112 (5784-50)

Sheet 1 of 2

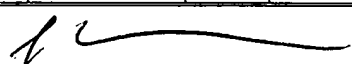
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**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant Of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	6
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
SR	1	EP	0 256 714	A2	Cetus Corporation	02-24-1988	—	11
SR	2	WO	89/06692	A1	Genentech, Inc.	07-27-1989	—	11

Examiner Signature		Date Considered	1/24/03
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<sup>1</sup> Unique citation designation number.

<sup>2</sup> See attached Kinds of U.S. Patent Documents.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

<sup>6</sup> Applicant is to place an "X" here if English language Translation is attached.

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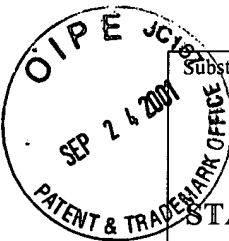
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**NON PATENT LITERATURE DOCUMENTS**

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) , volume-issue number(s), publisher, city and/or country where published.	T
SR	3	DIERKSHEIDE <i>et al.</i> (1999) "Fc Receptor Cross-Linking in the Presence of Interleukin-12 is a Potent Stimulus to Natural Killer Production of Interferon-gamma: Implications for Anti-Her2 Antibody Therapy," <i>Proceedings of the American Association for Cancer Research</i> 40: 77 (XP002171956)	
	4	FLEMING <i>et al.</i> (1999) "Phase I Trial of Recombinant Human Anti-Her2 Monoclonal Antibody (H) Plus Low-Dose Interleukin-2 (IL-2) in Patients with Solid Tumors," <i>Proceedings of the Annual Meeting of the American Society for Clinical Oncology</i> 18: A710 (XP001010378)	
	5	KOPRESKI <i>et al.</i> (1996) "Growth Inhibition of Breast Cancer Cell Lines by Combinations of Anti-P185 <sup>Her2</sup> Monoclonal Antibody and Cytokines," <i>Anticancer Research</i> 16: 433-436 (XP000973070)	
	6	LI <i>et al.</i> (1999) "Preparation and Characterization of a Human Interleukin-2 and Anti-Human Her2 ScFv Fusion Protein," <i>Proceedings of the American Association for Cancer Research</i> 40: 358 (XP002171954)	
	7	LI <i>et al.</i> (2000) "Chemical Conjugation of a Novel Antibody-Interleukin 2 Immunoconjugate Against c-erbB-2 Product," <i>Chinese Medical Journal</i> 113: 151-153 (XP000925246)	
	8	TAGLIAFERRI <i>et al.</i> (1996) "Differential Sensitivity to Non-Major Histocompatibility Complex-Restricted Recombinant Interleukin 2-Activated Lymphocyte Killing of Human Mammary Epithelial MCF-10A Cells Overexpressing Oncogenes or Protein Kinase A Subunits," <i>Clinical Cancer Research</i> 2: 207-214 (XP002171953)	
	9	WEINER <i>et al.</i> (1995) "Clinical Development of 2B1, A Bispecific Murine Monoclonal Antibody Targeting c-erbB-2 and Fc-gamma-RIII," <i>Journal of Hematotherapy</i> 4: 453-456 (XP002048529)	
	10	"Questions and Answers about NCI's Expanded Research with Herceptin (R)," <i>National Cancer Institute, Backgrounders, Online!</i> Bethesda, MD (September 28, 1998) URL: <a href="http://rex.nci.nih.gov/massmedia/back_pp_1-8">http://rex.nci.nih.gov/massmedia/back_pp_1-8</a> (XP002171955)	

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code (if known) <sup>5</sup>			

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Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
SR ↓	11	MEROPOL <i>et al.</i> (1996) "Daily Subcutaneous Injection of Low-Dose Interleukin 2 Expands Natural Killer Cells <i>in Vivo</i> Without Significant Toxicity," <i>Clin. Cancer Res.</i> 2: 669-677.	
	12	MEROPOL <i>et al.</i> (1998) "Evaluation of Natural Killer Cell Expansion and Activation <i>in Vivo</i> with Daily Subcutaneous Low-Dose Interleukin-2 Plus Periodic Intermediate-Dose Pulsing," <i>Cancer Immunol. Immunother</i> 46: 318-326.	

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SignatureDate  
Considered

1/24/03

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RTA01/2103788v1

<sup>1</sup> Unique citation designation number.<sup>2</sup> See attached Kinds of U.S. Patent Documents.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.<sup>6</sup> Applicant is to place an "X" here if English language Translation is attached.